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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,123	GREENE ET AL.	
	Examiner	Art Unit	
	Philip E. Stimpert	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 26 June 2007.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) 4-6 and 13-22 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3,7-12 and 23-30 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 14 June 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/26/04, 8/15/05.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I directed to a medical pump, and further of the species of Fig. 1 in the reply filed on 26 June, 2007 is acknowledged.

2. Claims 4-6 and 13-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 26 June, 2007.

Per telephonic interview conducted between the examiner and Mr. Michael Crabb on 10 July, 2007, claim 6 was recognized to be drawn to species 4 of the previous election requirement, and is accordingly added to the above list of claims withdrawn from consideration.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 7-12, and 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claim 1, the sixteenth line of the claim recites "a pump cycle." As line 3 of the claim also recites "a pumping cycle," it is unclear whether these limitations refer to a single cycle or to distinct cycles, and if the latter, what constitutes the distinction

between those cycles. The use of these terms without further clarification in the claim renders the claim indefinite.

6. Regarding claim 7, on line 2, the claim recites "a stroke frequency," a limitation also recited in line 17 of claim 1 from which claim 7 depends. This creates an ambiguity as to whether a single or plurality of stroke frequencies are being claimed, rendering the claim indefinite.

7. Claim 9 recites the limitation "the pump cycle" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim. It seems likely that this should instead read "the pumping cycle," and the examiner suggests amending the claim to that effect.

8. Further regarding claim 9, the claim recites the limitation "a beginning of the pump cycle." Since the pump cycle is, by definition, cyclical, any point within the cycle may be labeled the beginning. Therefore, the scope of protection sought by this limitation is not made clear and the claim is thereby rendered indefinite.

The examiner suggests altering "a beginning" to "a beginning of a compression stroke," or something similar which more clearly defines the scope of protection sought by the claim.

For the purposes of this office action, this limitation will be construed as "a beginning of a compression stroke."

9. Regarding claim 10, the claim recites the limitations "the middle of the pumping cycle" and "the start of the pumping cycle," on lines 7-9 of the claim. There is insufficient antecedent basis for these limitations in the claim. Further, for the same

reasons as the limitation "beginning of the pump cycle" in claim 9, these limitations do not adequately define the scope of the invention.

For the purposes of this office action, these limitations will be construed to mean "the end of the compression stroke of the pumping cycle" and "the start of the compression stroke of the pumping cycle" respectively.

10. Claim 23 recites the limitation "the pump cycle" in line 20 of the claim. There is insufficient antecedent basis for this limitation in the claim. It seems likely in this case as well that this limitation should read "the pumping cycle," and the examiner suggests amending the claim to that effect.

11. Regarding claim 25, the fifteenth line of the claim recites "a pump cycle." As line 4 of the claim also recites "a pumping cycle," it is unclear whether these refer to a single cycle or to distinct cycles, and if the latter, what constitutes the distinction between those cycles. The use of these terms without further clarification in the claim renders the claim indefinite.

For the purposes of this office action, claims 1 and 25 will be construed such that the limitations "pump cycle" and "pumping cycle" both refer to a single pump cycle.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-9, 11 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Epstein et al. (US. 5,464,392).

14. Regarding claim 1, Epstein et al. teach a medical pump for use with a pumping chamber (20), comprising:

- a pumping element (198) adapted to intermittently pressurize the pumping chamber (20) during a pumping cycle
- a pressure sensor (40 or alternatively 308) adapted to detect the pressure exerted by the pumping element (198) on the pumping chamber (20)
- a position sensor (see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (198, operatively associated through pumping piston 272 (also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (198)
- a processing unit (48) in electronic communication with the pressure sensor (40 or 308) and the position sensor
- a memory (404) coupled to the processor unit containing programming code executed by the processing unit to process pressure data from the pressure sensor and position data from the position sensor (col. 28, ln. 44 to col. 29, ln. 3, also equations 1-2 in col. 31) to determine a calculated stroke volume of the pump for a pump cycle and to adjust a stroke frequency (col. 27, ln. 25) of the pump to compensate for variation between the calculated stroke volume and a desired dosage rate.

15. Regarding claim 2, Epstein et al. teach that the pressure transducer (40 or 308) is the only pressure sensor included in the medical pump.

16. Regarding claim 3, Epstein et al. teach that the pressure transducer (40 or 308) is directly connected to the pumping element (198, see col. 19, ln. 30-39).

17. Regarding claim 7, Epstein et al. teach that the programming code executed by the processor sets a stroke frequency (col. 27, ln. 25) for the desired dosage rate based on a nominal stroke volume (A*100 or A*88, col. 31, ln. 12-18) and adjusts the stroke frequency to compensate for variation between the calculated stroke volume and the nominal stroke volume (according to equations 1-2 in col. 31).

18. Regarding claim 8, Epstein et al. teach that their pumping chamber has an outlet valve, and that the programming code executed by the processing unit processes pressure data from the pressure sensor to determine when the valve opens (col. 32, ln. 5-8). In this interpretation, the processing unit is processing the pressure data in order to determine when to actuate the valve, rather than processing the pressure data so as to identify from the pressure state of the pumping chamber when the valve has opened.

19. Regarding claim 9, Epstein et al. teach that the programming code executed by the processing unit processes pressure data and position data to determine a calculated pressurization volume from a beginning of the pump cycle to the point when the outlet valve opens, and uses the calculated pressurization volume to determine the calculated stroke volume.

In particular, in relation 1 in column 31, a distributed version of the expression would contain the term A*N2, which constitutes a calculated pressurization volume, and

is used in that expression to calculate the effective volume, which constitutes a calculated stroke volume.

20. Regarding claim 11, Epstein et al. teach a cassette (shown in Fig. 4) for defining the pumping chamber (col. 3, ln. 8-16).

21. Regarding claim 25, Epstein et al. teach a medical pump for use with a cassette (as shown in Fig. 4) having a pumping chamber (col. 3, ln. 8-16), comprising:

- a pumping element (198) adapted to intermittently pressurize the pumping chamber (20) during a pumping cycle
- a pressure sensor (40 or 308) adapted to detect the pressure exerted by the pumping element on the pumping chamber
- a position sensor (see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (198, operatively associated through pumping piston 272 (also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (198)
- a processing unit (48) in electronic communication with the pressure sensor (40 or 308) and the position sensor
- a memory (404) coupled to the processor unit containing programming code executed by the processing unit to process pressure data from the pressure sensor (40 or 308) and position data from the position sensor (col. 28, ln. 44 to col. 29, ln. 3, also equations 1-2 in col. 31) to determine a calculated stroke volume of the pump for a pump cycle and to adjust a stroke frequency (col.

27, ln. 25) of the pump to compensate for variation between the calculated stroke volume and a desired pump flow rate.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. Claims 10 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Epstein et al. in view of Madsen et al. (US 4,850,805).

24. Regarding claim 10, Epstein et al. substantially teach the invention of claim 9 from which claim 10 depends (see above rejection of claim 9 under 35 U.S.C. 102(b) for detailed discussion). Epstein et al. do not teach the calculation of stroke volume using a ratio of pumping chamber expansion (hereafter, "pumping chamber expansion" will be used interchangeably with "compliance"). The patent to Madsen et al. is directed to a pump control system for a cassette type medical pump. In particular, Madsen et al. address the problem of accurately measuring the flow volumes of this type of pump, (col. 1, ln. 32-43), especially due to compliance errors. Madsen et al. teach the following method for control of an infusion pump: "The pumping pressure peak during pumping and the pressure minimum during filling are detected to determine the portion of a pumping cycle required to make the transition between these two pressure levels. The difference between the two pressure levels divided by the transition portion of the pumping cycle gives a measure of the compliance of the pump chamber. The ratio of

the compliance measure to the total cycle, when multiplied by the nominal chamber volume, gives a measure of unpumped volume, which is subtracted from the nominal volume to give the volume actually pumped during a pump cycle," (abstract, Madsen et al.). Further, Madsen et al. teach that their "control technique gives particularly precise control at low fluid delivery rates where precision is especially important," (Madsen et al., col. 2, ln. 10-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the pressure data collected by the pressure sensor of Epstein et al. to calculate the actual volume of fluid pumped, correcting for compliance, in order to more accurately control volumes pumped at low rates. In particular, it would have been obvious to one of ordinary skill in the art to program the processing unit to determine a change in pressurization volume by subtracting the calculated pressurization volume from a nominal pressurization volume, determine a change in stroke volume by multiplying the change in pressurization volume by a ratio of pumping chamber compliance at the end of the compression stroke of the pump to the compliance at the start of the compression stroke, and determine the calculated stroke volume based on the change in stroke volume.

25. Regarding claim 23, the combined references teach a medical pump for use with a pumping chamber (Epstein et al., col. 3, ln. 8-16), comprising:

- a pumping element (Epstein et al., 198) adapted to intermittently pressurize the pumping chamber during a pumping cycle
- a pressure sensor (Epstein et al., 40 or 308) adapted to detect the pressure exerted by the pumping element on the pumping chamber

- a position sensor (Epstein et al., see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (Epstein et al., 198, operatively associated through pumping piston 272 (Epstein et al., also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (Epstein et al., 198)
- a processing unit (Epstein et al., 48) in electronic communication with the pressure sensor (40 or 308) and the position sensor
- a memory (Epstein et al., 404) coupled to the processing unit, where the memory contains programming code executed by the processing unit to process pressure data from the pressure sensor and position data from the position data from the position sensor (Epstein et al., col. 28, ln. 44 to col. 29, ln. 3, also equations 1-2 in col. 31) to:
    - set a stroke frequency (col. 27, ln. 25) for a desired dosage rate based on a nominal stroke volume (A*100 or A*88, col. 31, ln. 12-18)
    - determine when an outlet valve of the pumping chamber opens (col. 32, ln. 5-8)
    - determine a calculated pressurization volume from a beginning of a compression stroke of the pumping cycle to the point when the outlet valve opens (col. 31, relation 1, A*N2)
    - determine a change in pressurization volume by subtracting the calculated pressurization volume from a nominal pressurization volume (col. 31, relation 1)

- determine a change in stroke volume by multiplying the change in pressurization volume by a ratio of pumping chamber compliance at the end of the compression stroke of the pumping cycle to the pumping chamber compliance at the start of the compression stroke of the pumping cycle (according to the combination)
- determine a calculated stroke volume based on the change in stroke volume (according to the combination), and
- adjust the stroke frequency to compensate for variation between the calculated stroke volume and the nominal stroke volume (according to the combination).

26. Regarding claim 24, the combined references teach the use of a cassette for defining the pumping chamber (as shown in Fig. 4 of Epstein et al).

27. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Epstein et al. in view of Holst et al. (US 2003/0055375).

28. Epstein et al. substantially teach the invention of claim 1 from which claim 12 depends (see above rejection of claim 1 under 35 U.S.C. 102(b) for discussion). Epstein et al. do not teach the practice of averaging multiple calculated stroke volumes to produce a single calculated stroke volume. The patent to Holst et al. is directed to a pumping control method for a cassette pump. In particular, Holst et al. teach the acquisition of pressure samples, and that "the plurality of samples are averaged to minimize any pressure sensing variations," (paragraph 35). As discussed above, the

calculated stroke volume is in part dependent upon the pressure data. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a calculated stroke volume comprising multiple calculated stroke volumes averaged together, in order to minimize the effects of pressure sensing variations in the calculations.

29. Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Epstein et al. in view of Butterfield (US 2001/0007636).

30. Regarding claim 26, Epstein et al. teach a medical pump for use with a cassette (see Fig. 4) having a pumping chamber, comprising a processing unit (Epstein et al., 48) and a memory (Epstein et al., 404) coupled to the processing unit, wherein the memory contains programming code executed by the processing unit to control operation of the pump to deliver a desired flow rate. Epstein et al. do not teach the particular values of a flow rate of about 1 ml/hr, bolus volumes less than 2 microliters or intervals of no more than twenty seconds. The patent to Butterfield is directed to a system and method for increased flow uniformity in an infusion pump. In particular, Butterfield teaches that the "need for minimal fluctuation of the flow rate can become most acute in the lower ranges of flow typically produced by commercial peristaltic infusion devices, such as the range from 0.1 to 1.0 ml/hr," (Butterfield, paragraph 15). Further, Butterfield teaches that the Emergency Care Research Institute "rates an infusion pumps [sic] flow uniformity as 'excellent' if less than 20 seconds elapse between 'flow steps' at the 'lowest rate programmable,'" (Butterfield, paragraph 16). In

one hour, there are 180 periods twenty seconds long. Therefore, at the lowest rate discussed by Butterfield above, 0.1 ml/hr, emission of a bolus no less frequently than every 20 seconds would engender a bolus volume of no more than 0.56 microliters, which is less than 2 microliters. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the medical pump of Epstein et al. so as to employ a bolus volume less than 2 microliters supplied at a frequency greater than once every 20 seconds in order to provide an excellent flow uniformity as defined by the Emergency Care Research Institute. It would further be obvious to continue to use the same small bolus volume at larger flow rates such as 1.0 ml/hr in order to maintain excellent flow uniformity (which would be maximized by most closely approximating continuous flow).

31. Regarding claim 27, Epstein et al. teach that the medical pump further comprises:

- a pumping element (Epstein et al., 198) adapted to intermittently pressurize the pumping chamber during a pumping cycle
- a pressure sensor (Epstein et al., 40 or 308) adapted to detect the pressure exerted by the pumping element on the pumping chamber
- a position sensor (Epstein et al., see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (Epstein et al., 198, operatively associated through pumping piston 272 (Epstein et al., also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (Epstein et al., 198)

- wherein the processing unit is in electronic communication (see Fig. 1, and col. 29, ln. 20) with the pressure sensor (Epstein et al., 40 or 308) and position sensor
- wherein the memory contains programming code executed by the processing unit to process pressure data from the pressure sensor and position data from the position sensor to control operation of the pump (see col. 29, calculation of flow rate from effective volume, which is based of position and pressure data)

32. Regarding claim 28, the combined references teach that the memory contains programming code executed by the processing unit to control the operation of the pump in a closed loop control system. For example, Epstein et al. teaches that "the processor is operative in response to the measured pressure data to adjust the reciprocating motion of the pumping piston to adapt desired to actual fluid flow rates," (col. 21, ln. 54-57). Given that "PROM 404 includes preselected address locations thereof the code specifying the program for the system I/O and pump control processor 374" (col. 23, ln. 4-6), the processor and memory, together with the program instructions and connections to the sensors and actuators, constitute a closed loop control system which controls operation of the pump.

33. Regarding claim 29, according to the combination, it would be obvious to provide programming code in the memory to be executed by the processing unit so as to control operation of the pump to deliver a flow rate of about 0.1 ml/hr with bolus volumes of less

than delivered in increments of not greater than twenty seconds between the bolus volumes.

34. Regarding claim 30, the claim is directed to a “flow rate of up to 1000 ml/hr.,” which delineates a range from 0-1000 ml/hr. The combined references teach flow rates of 0.1-1.0 ml/hr which values fall within the range specified. Thus, the combined references teach the limitation that the memory contains programming code executed by the processing unit to control operation of the pump to deliver a flow rate of up to 1000 ml/hr.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip E. Stimpert whose telephone number is (571) 270-1890. The examiner can normally be reached on Mon-Fri 8:00AM-5:00PM, Alt. Fridays, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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20 Jul 07

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PRIMARY EXAMINER